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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,799	03/04/2004	Sacha Adrianus Fokke Taco Van Hijum	2001-1043-2	3865

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EXAMINER

PROUTY, REBECCA E

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1652

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/791,799	Applicant(s) VAN HIJUM ET AL.	
	Examiner Rebecca E. Prouty	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-21 is/are pending in the application.
- 4a) Of the above claim(s) 2,7-11 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-6 and 12-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Claim 3 has been canceled. Claims 1, 2, 4-11 and newly presented claims 12-21 are still at issue and are present for examination. Claims 2 and 7-11 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/13/06 furthermore, as new claim 21 depends from claim 8 it is withdrawn as well.

Applicants' arguments filed on 4/16/07, have been fully considered and are not deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claims 1, 4-6 and 18-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of producing levan using *Lactobacillus reuteri* strain 121 or a microorganism transformed with a nucleic acid encoding the levansucrase of SEQ ID NO:11, does not reasonably provide enablement for methods of producing levan using any *Lactobacillus* strain capable of producing a fructosyltransferase having 85% identity to SEQ ID NO:11. The specification does not enable any person skilled in the art to which it pertains, or

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with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The rejection is explained in the previous Office Action.

Applicants argue that one skilled in the art would be able to practice the claimed invention in view of the state of the art of recombinant techniques and the teachings of the specification, one of ordinary skill in the art would have been capable of performing any modifications that would have been necessary to practice the claimed invention. Applicants further argue that the same scope was issued in the parent applications which matured into U.S. Patent Nos. 6,635,460 and 6,730,502.

Applicants are reminded that every application is examined on its own merits. However, to the extent that the instant rejection might also be applicable to the claims of the issued patents, the instant Office Action contains the signature of the Group Director as required by MPEP 1003. While methods to produce variants of a known sequence such as site-specific mutagenesis, random mutagenesis, etc. are well known to the skilled artisan, producing variants useful as fructosyltransferases producing a fructan having β (2-6) linked fructose residues requires that one of ordinary skill in the art know or be provided with guidance for the selection of which of the infinite number of variants have the activity. Without such

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guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the virtually infinite possibilities. For the rejected claims this would clearly constitute **undue** experimentation. Guo et al. teach that the percentage of random single substitution mutations which inactivate a protein for the protein 3-methyladenine DNA glycosylase is 34% and that this number appears to be consistent with other studies in other proteins as well. The data of Guo et al. shown in Table 1 further shows that the percentage of active mutants for multiple mutants appear to be exponentially related to this by the simple formula $(.66)^x \times 100\%$ where x is the number of mutations introduced. Applying this estimate to the instant protein, 85% identity allows up to 118 mutations within the 792 amino acids of SEQ ID NO:7 and thus only $(.66)^{118} \times 100\%$ or $5.1 \times 10^{-20}\%$ of random mutants having 85% identity would be active. Current techniques (i.e., high throughput mutagenesis and screening techniques) in the art would allow for finding a few active mutants within several hundred thousand inactive mutants (despite even this being an enormous quantity of experimentation that would take a very long time to accomplish) but finding a few mutants within several billion or more as in the instant claims would not be possible. While enablement is not precluded by the necessity for routine

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screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. Such guidance has **not** been provided in the instant specification. Applicants further argue that as long as the specification discloses at least one method for practicing the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. However, it is noted that applicants claims recite not one method but an enormous genus of different methods as methods using different fructosyltransferases or different *Lactobacillus* strains are distinctly different methods. When a genus is claimed the specification must enable how to make and use the entire scope of the genus recited. As described above, the specification in the instant case clearly fails to do so. Therefore, the rejection is maintained.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6, 12, 15, and 18 are rejected under 35

U.S.C. 102(b) as being anticipated by either of Van Geel-

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Schutten et al. (1998) or Van Geel-Schutten et al. (1999). The rejection is explained in the previous Office Action.

Applicants argue that the (1999) reference does not qualify as prior art as the present application is a continuation-in-part application of US Application Serial No. 09/995,587, filed on November 29, 2001, which is a continuation-in-part application of US Application Serial No. 09/604,958, filed on June 28, 2000. The (1999) reference was published in July of 1999 with Gerritidina Hendrika Van Geel-Schutten and Lubbert Dijkhuisen as co-authors and therefore was published by the current inventors less than 12 months before the present filing date and can not constitute prior art under 35 USC §102(b). The work disclosed in that article now appears in the present application. Accordingly, the article merely describes applicant's own work and does not qualify as prior art under any other provisions of 35 USC 102.

However, this is not persuasive because while the present application claims priority to the filing date of grandparent application 09/604,958, the instant claims have not been granted the benefit of the filing date of this application as the grandparent application fails to provide support for the instant claims. In particular the grandparent application does not disclose SEQ ID NO:11 as recited in the instant claims. SEQ ID

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NO:11 was first disclosed in parent application 09/995,587, filed on November 29, 2001 and thus the effective date used for art purposes of the instant claims is 11/29/01. The Van Geel-Schutten et al. (1999) reference was published more than one year prior to this date and thus does qualify as art under 102(b). Furthermore, it is noted that even if applicants presented claims which find support in the grandparent application, the Van Geel-Schutten et al. (1999) reference would qualify as art under 102(a) as the authorship of the reference and inventorship of the instant application are different.

Applicants further argue that neither the Van Geel-Schutten et al. (1998) or Van Geel-Schutten et al. (1999) publications teach or suggest subjecting a fructose source to a *Lactobacillus* strain under non-growth conditions and isolating the recited fructans. However, this is not persuasive as Table 2 of the Van Geel-Schutten et al. (1998) paper clearly discloses EPS production by washed cell suspensions and dialysed supernatants of LB 121 cultures incubated under anaerobic conditions at 37 °C, pH 5.5 with 33 g/l sucrose followed by ethanol precipitation of the EPS and Table 3 of the Van Geel-Schutten et al. (1999) paper clearly discloses EPS production by washed cell suspensions and dialysed supernatants of LB 121 cultures incubated at 37 °C with sucrose followed by ethanol

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precipitation of the EPS. These disclosures clearly meet all limitations of claims 1, 12, and 18. Furthermore, each of van Geel-Schutten et al. (1999) and van Geel-Schutten et al. (1998) teach the further hydrolysis of the fructan produced and van Geel-Schutten et al. (1999) also teach the methylation of the fructan further anticipating claims 6 and 15.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4, 5, 13, 14, 16, 17, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of van Geel-Schutten et al. (1999) and van Geel-Schutten et al. (1998). The rejection is explained in the previous Office Action.

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Applicants argue that there is no indication that under non-growth conditions that the strains would be capable of producing a polysaccharide, let alone a fructan-containing polysaccharide as recited in the claimed invention and thus there is no teaching to isolate the fructans or to add the fructans to a food composition. This is not persuasive as each of the references clearly identify the exopolysaccharide produced by strain *Lactobacillus reuteri* strain 121 as a fructan.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4-6, and 12-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7 and 8 of U.S. Patent No. 6,730,502. The rejection is explained in the previous Office Action.

Applicants argue that the present claims recite steps of subjecting a fructose source to a *Lactobacillus* strain under non-growth conditions, isolating the recited fructans, and/or adding the recited fructans to a food product. As these recitations are not disclosed in claims 7 and 8 of U.S. Patent No. 6,730,502, the instant claims would be obvious in view of claims 7 and 8 of U.S. Patent No. 6,730,502. It should be noted that new claims 18-20 do not in fact recite subjecting a fructose source to a *Lactobacillus* strain under non-growth conditions and the limitation of adding the recited fructans to a food product was addressed in the previous action. Furthermore, while the claims of the patent do not expressly recite subjecting a fructose source to a *Lactobacillus* strain under non-growth conditions they recite combining sucrose with a host cell producing a fructosyltransferase as the only step for producing the fructo-oligosaccharide but there is no step of incubating the cells under growth conditions recited such that

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the recitation of the patent claims inherently meets the limitation recited in the instant claims. Furthermore, while the patented claims do not recite isolating the product, this would have been obvious to one of ordinary skill in the art given the method of the patented claims. As such the rejection is maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rebecca Prouty/
Primary Examiner
Art Unit 1652


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